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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,983	08/17/2000	Michael L. Lehrman	ILIF01-00056	6192
23990	7590	12/10/2003	EXAMINER	
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			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,983

Applicant(s)

LEHRMAN ET AL.

Examiner

Joseph F Weiss Jr.

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4, 6, 11-12, 14 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Shannon, Jr. et al. (US 5123425).

In regards to claims 1 & 11, Shannon discloses an apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs said apparatus comprising at least one microphone (24 and supporting text) which detects breathing sounds and which generates signals representative of such; a controller (20) coupled to the microphone capable of receiving such breathing sound signals and identifying signals indicative of the onset of said physiological process //(e.g a partially occluded airway) event before cessation of breathing occurs and capable of generating an alarm signal (col. 3 lines 25-50), and a stimulus generator (26 & 28 and supporting text) capable of receiving such alarm signals creating a stimulus and is fully capable of causing said person to move said person's head backwards to terminate said physiological process before cessation of breathing occurs. (note the abstract last full sentence namely the phrase genioglossus and related muscles. Genioglossus muscles are the muscles that control the tongue and "related muscles" are viewed as

any other muscle that could be stimulated that are related to the genioglossus muscles that can also be simulated to cause the same effect, clearance of the airway thus including those muscles that would tilt back a patient's head & cause the tongue to clear the airway. See excerpt of the Core Textbook of respiratory Care practice, chapter 12, on CPR note fig 12-1, the illustration of the mechanical stimulation of the user's muscles to cause airway clearance via genioglossus muscle stimulation).

In regards to claims 2 & 12, Shannon discloses the use of an electrical current source (note the use of electrodes, an electrical current source).

In regards to claims 4 & 14, Shannon discloses the use of an electrical current source (note the use of electrodes, an electrical current source).

In regards to claims 6 & 16, Shannon discloses the use of at least one filter (204) for filtering the signal, the filtered signal being indicative of breathing patterns and discerned by the controller as being a indicative of the onset of obstructive sleep apnea/(e.g. partially occlude airway)to include the capability to detect patterns of said person that occurs at the onset of an obstructive sleep apnea even before cessation of breathing occurs.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-8, 10, 17-18, 20-22 & 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon.

In regards to claims 7 & 17, Shannon discloses that an air flow sensor can be utilized with the device, thus one of ordinary skill in the art would consider applicant's use of an air flow sensor with the instant device to be an obvious modification to the device of the prior art. (Col. 3, line 30-35).

In regards to claims 8 & 18, Shannon discloses the instant application's invention, to include the capability to detect patterns of said person that occurs at the onset of an obstructive sleep apnea even before cessation of breathing occurs, except for an express recitation of the use of "software." However, software is nothing more than a series of commands in an algorithm to be executed a given way, based upon input, feedback, conditions and events. The electronic's module of Shannon performs such algorithmic tasks and thus would be viewed by one of skill in the art as being "programmed" and hence to be comprised of what would be understood as "software." Accordingly, such a limitation under a standard of obviousness would not distinguish the instant application's claimed invention over that of the prior art. (See fig 7 and supporting text in col. 4 lines 5-42).

In regards to claims 10 & 20, operation during $\frac{1}{2}$ of the breathing cycle, the device of Shannon is fully capable of being operated in a manner wherein the controller operates the device for only "one half" of a respiratory cycle.

In regards to method claims 21-22 & 24-29, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-2, 4, 6-8, 10-12, 14, 16-18 & 20.

5. Claims 9 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 8 & 18 above, and further in view of Schecter et al (US 5058600).

In regards to claims 9 & 19, Shannon substantially discloses the instant application's claimed invention to include the capability of detecting a breathing signal associated with the onset of an obstructive sleep apnea event, but does not explicitly disclose using software with Fast Fourier Transform (FFT) analysis. However, Schecter disclose such (Note abstract statement that acoustic signals are processed using FFT). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schecter and used them with the device of Shannon. The suggestion/motivation for doing so would have been to effectively process the acoustical data for diagnostic analysis. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

6. Claims 3 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 1 & 11 above, and further in view of Lambert (US 5652566).

In regards to claims 3 & 13, Shannon substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a vibrator or a

sound generator. However, Lambert disclose such (24). The references are analogous since they are from the same field of endeavor, the medical monitoring arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lambert and used them with the device of Shannon. The suggestion/motivation for doing so would have been to provide additional/redundant alarm systems, insuring the user is stimulated. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 23, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 3 & 13.

7. Claims 5 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 1 & 11 above, and further in view of Teodorescu et al (US 6011477).

In regards to claims 5 & 15, Shannon substantially discloses the instant application's claimed invention to include the capability to detect patterns of said person that occurs at the onset of an obstructive sleep apnea even before cessation of breathing occurs, but does not explicitly disclose a remote base station. However, Teodorescu disclose such (28). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's

invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Teodorescu and used them with the device of Shannon. The suggestion/motivation for doing so would have been to give the user more range/freedom of movement during use of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

8. Applicant's arguments filed 17 Nov 03 have been fully considered but they are not persuasive.

In regards to the 35 USC 102 & 103 rejections, applicant's amendment is proper and responsive, but does not resolve the issues, therefore the rejections are retained, as modified above in response to applicant's amendments.

Note generally:

Applicant's arguments fail to comply with **37 CFR 1.111(b)** because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with **37 CFR 1.111(c)** because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to the 35 USC 102 arguments:

At the outset the examiner notes that applicant points to no empirical differences in structure between the prior art device and the instantly claimed invention. Instead applicant points to several "capabilities" "functions" "intended uses/results" of the very same structure that the prior art discloses, and then asserts that those same features in the prior art cannot perform those very same "capabilities" "functions" "intended uses/results." Please explain?

In response to applicant's argument that the intended use/result language of "before cessation of breath," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant points to no structure in his invention that flows as a distinction from the device of the prior art.

There is no teaching in the prior art that the airway must be fully obstructed before it will act upon ameliorating an apneic event.

Before cessation of breath does not correlate to the airway not being obstructed, there is a gap in applicant's logic in asserting that this language to one of ordinary skill in the art would understand that such language inherently means the airway is not obstructed. But instead it at best can only arguably mean the airway is not "fully obstructed" to cause cessation of breath.

The Shannon reference makes no such correlation to onset empirically meaning the airway is completely obstructed, contrary to applicant's assertion that this is clear.

None of the fragments applicant points suggest, let alone clearly state this correlation of terms. Therefore applicant's arguments are not persuasive, and the rejection it retained as noted above.

Applicant points to several portions of Shannon then interprets them as only/absolutely meaning that Shannon only can operate after complete obstruction of the airway. Yet, Shannon discloses it detects snoring a common indicator of partial airway obstruction. Applicant points to the fact that Shannon states it **DETECTS APNEA ONSET**, onset is not complete obstruction, complete obstruction is a **FULL BLOWN APNEA EVENT**, hence using logic and canons of construction one of ordinary skill would find that **ONSET** means the beginning of obstruction, i.e. a partial obstruction, i.e. snoring.

Applicant's use of non-limiting pre-amble language of Shannon's claims does not assist him in his position. Claims are read in light of the written description. The written description as noted in the immediately preceding paragraphs does not use "obstruction" only and solely means complete obstruction as applicant asserts, it encompasses the entire spectrum of de minimus obstruction to complete obstruction and thus the partial obstructions therebetween. Hence applicant's bias claim interpretation is not persuasive.

In regards to applicant's assertion that somehow one possible mode of operation of Shannon translates into **STRUCTURAL DIFFERENCES** please point to structure not operation and function. The setting of levels or thresholds are not structure, and the device is fully capable of having the level set to detect partial obstructions.

Regarding the capabilities of applicant's controller, it is noted there is no structure to undergird this "capability" in the claims nor reasonably inferable from the claims by reading the written description, thus this is more of hope on the part of applicant than

any actual structural distinction, thus amounting to a difference without a distinction. Claim the specific structures of your controller that make it distinct.

Regarding applicant's assertion that "apneic event" absolutely only means complete obstruction please present the evidence to this. The examiner cites class 128/ 204.23 which is replete with the terminology of "partial obstruction" as an apneic event.

Regarding the issue of stimulation of genioglossus and related muscles and applicant's assertion that the prior art will stimulate muscles to work against each other but applicant's will not, to assert such means that the prior art would not work, paralysis of the muscle would be the result, hence applicant is saying the prior art reference is invalid by dint of being inoperative, yet presents no evidence to this affect. Patents are presumed valid, this is not a forum to challenge a patent's validity, the manner of stimulation would be what one of ordinary skill in the art would understand what was meant by muscle stimulation, not what applicant hopes. If applicant's invention is targeted stimulation of a specific set of muscles to resolve the onset of an occlusion of the airway then claim it, when claiming in a broad nebulous manner then arguing specifics is not how to claim the invention, the scope of the prior art encompasses applicant's current manner of claiming what is being asserted as the patentably distinct difference.

Fro the reason's above applicant's 102 arguments are found non-persuasive. In regards to the 35 USC 103 rejections:

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejections meet these criteria, are all in the relevant art, are properly motivated in light of the knowledge of one of ordinary skill in the relevant art, hence the USPTO had meet its burden and shifted the burden of proof to applicant, it is applicant who has not meet his burden of proof on rebuttal that is the current legal state of the case, not that the USPTO has not yet meet its burden. Applicant states he has reiterated his prior arguments, hence the examiner reiterates his prior arguments and they are presented below:

The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.

Applicant concludes without a reasoned basis that Shannon does not analyze breathing sounds, which is contrary to the disclosure of Shannon as read by one of ordinary skill in the art.

The apparatus of Schecter is not relevant to the objection, just its teaching of using FFT to detect breathing sounds as one of ordinary skill in the prior art would appreciate it could be used in light of state of the art and the teachings.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

Regarding the 103 rejection of Lambert again the examiner notes, The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.

Regarding the need for a monitor, the fragment of Lambert applicant points to is merely illustrative of the many needs for monitoring, please read the reference as a hole.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

Regarding the 103 rejection of Teodoreescu again the examiner notes, The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.


In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

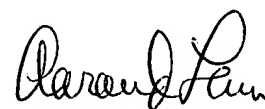
Furthermore, as noted the 35 USC 102 rejection has been modified to address the new claim limitations, hence in regards to all 35 USC 103 arguments directed toward the new differences without distinctions in the claims they are addressed and moot in light of the modifications of the 102 rejections.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Core Textbook of Respiratory Care Practice

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Jfweiss
12/5/03


Aaron J. Lewis
Primary Examiner